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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/190,246	11/13/1998	MARK PARRINGTON	1038-865MIS	6436

7590 01/26/2004

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EXAMINER

WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/190,246

Applicant(s)

PARRINGTON ET AL.

Examiner

Michael C. Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 2-18-03, 7-7-03 and 11-10-03.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,6,8-10 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6,8-10 and 14-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11-30-03
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Applicant's amendment filed 11-10-03, fixing the status of the US Patent applications on pg 5, line 11, pg 6, line 30, pg 7, line 6, pg 7, line 12, pg 7, line 6, and fixing the application number on pg 15, lines 16 and 19, has been entered.

The amendment to the specification filed 2-18-03 on pg 20, line 10, has not been entered because the page numbers are improper. Claims 36-38 were canceled as requested in the amendment filed 2-18-03. Claims 1 and 14-16 were amended as requested on 2-18-03.

Support for the amendments made to claim 1 were provided on 7-7-03 taken with the correct page numbers provided on 11-10-03.

Claims 1, 6, 8-10 and 14-19 remain pending and under consideration in the instant application.

Applicants arguments filed 2-18-03 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The term "proteins" in claim 6 should be ~~protein~~.

The term "promoter sequence" in claim 10 should be ~~promoter~~—to reflect the promoter in claim 1.

### ***Specification***

The attempt to incorporate subject matter into this application by reference to US application 08/923558 remains improper. The method by which the control mice were immunized with a vector in Example 3 on pg 25, line 16, was "as described in my previous application 08/923,558, except that the muscles were not treated with cardiotoxin". However, the method of delivery of vectors for the control immunization is essential to determine the immunogenicity of the vector claimed. Therefore, the method described in '558 and the results thereof should be included in the instant specification so that one of skill would be able to obtain adequate immunogenicity as compared to controls.

The status of applications on pg 9, line 13 and 29, pg 15, line 14, 15, 18 and 19, pg 23, line 25, pg 24, line 23, pg 25, line 18, pg 26, lines 24 and 25, must be updated as necessary.

The addition of the ATCC designation 203461 deposited 11-18-98 on page 22, line 10 remains new matter because the deposit information provided indicates the deposit was received 11-12-98. The attempt to amend the specification on 2-18-03 has not been entered because the page numbers are improper.

Applicants have not provided any evidence that the inventors of the instant application deposited 203461. Such evidence cannot be found on the deposit form filed 11-25-98 as asserted or in the specification as originally filed.

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The deposit form filed 11-25-98 states the deposit will be maintained according to the provisions of the Budapest Treaty; however, the administrator of the patent depository signed it. If a deposit is made under the provisions of the Budapest Treaty, an affidavit or declaration must be filed by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. In this case, no such affidavit, declaration or statement has been received. However, applicants point to the paragraph bridging pg 21-22 which states "certain vectors... ..have been deposited with the American Type Culture Collection (ATCC)" and will become will become available to the public and that non-viable deposits will be replaced. This is acceptable because the application was filed with a declaration signed by the inventors.

***Claim Rejections - 35 USC § 112***

The written description rejection of claims 1, 6, 8-10 and 14-19 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention has been withdrawn. The limitation of an RSV protein or a truncated RSV F or G protein lacking the transmembrane anchor and cytoplasmic tail can be found in claim 7 as originally filed.

I. Claims 1, 6, 8-10 and 14-19 remain rejected under 35 U.S.C. 112, first paragraph (new matter), as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Support for the limitation of a truncated RSV F or G protein that lacks the transmembrane anchor and cytoplasmic tail can be found in original claim 7.

Support for inserting the second DNA sequence into a non-essential region for replication of the first DNA sequence as claimed is found on pg 8, lines 23-25.

Support for a third DNA sequence having a pair of splice sites that prevent aberrant mRNA splicing *in vivo* is found in original claim 12.

The third DNA sequence being located between the first DNA sequence and the promoter remains new matter. Applicants argue support is found in Fig. 2B. Applicants'

argument is not persuasive. Splice sites in a third DNA sequence cannot be found. It is unclear which portions of the two vectors in Fig. 2B correlate to the first, second and third DNA sequences claimed.

The specification does not teach the first, second, and third DNA sequences are under control of a single promoter. Applicants have not addressed this portion of the rejection.

Therefore, claim 1 remains new matter.

II. Claims 1, 6, 8-10 and 14-19 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vector having the first and second DNA sequences as claimed, does not reasonably provide enablement for any third DNA sequence having a pair of splice sites that prevent aberrant mRNA splicing *in vivo* as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for reasons of record.

Support for the limitation of a truncated RSV F or G protein that lacks the transmembrane anchor and cytoplasmic tail can be found in original claim 7.

Support for inserting the second DNA sequence into a non-essential region for replication of the first DNA sequence as claimed is found on pg 8, lines 23-25.

Support for a third DNA sequence having a pair of splice sites that prevent aberrant mRNA splicing *in vivo* is found in original claim 12.

The third DNA sequence being located between the first DNA sequence and the promoter remains not enabled. Applicants argue such a construct is found in Fig. 2B.

Applicants' argument is not persuasive. Splice sites in a third DNA sequence cannot be found. It is unclear which portions of the two vectors in Fig. 2B correlate to the first, second and third DNA sequences claimed. If the third DNA sequence in Fig. 2B is the rabbit  $\beta$ -globin intron, it is unclear whether that intron prevents aberrant mRNA splicing and what other possible sequences might have the same structure or function.

The specification does not teach the first, second, and third DNA sequences are under control of a single promoter. Applicants have not addressed this portion of the rejection.

III. Claims 1, 6, 8-10 and 14-19 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it does not clearly set forth the structure or function of the three DNA sequences in the vector.

The first DNA sequence is indefinite because it is unclear how "complementary" the DNA sequence is to the RNA genome. In addition, it is unclear whether the phrase "and having the complement of complete alphavirus RNA genome replication" refers to the first DNA sequence or the RNA genome. It is unclear what applicants consider "complete" alphavirus RNA genome replication regions that permit *in vivo* replication. Replication regions that permit *in vivo* replication are not defined in the specification or in the art at the time of filing. It is unclear whether alphavirus regions required for replication *in vivo* in any species is the same. Overall, the structure or function of the first DNA sequence is not clearly set forth. Applicants' argue the rejection has been

overcome because the claim has been amended to "wholly complementary to at least part of an alphavirus genome". Applicants' argument is not persuasive. The first sequence is not necessarily the complement of the entire alphavirus RNA genome because it is "wholly complementary to at least a part of an alphavirus RNA genome." It is unclear what applicants consider the whole complement of a part of the alphavirus genome. It is unclear whether the first sequence is limited to the complement of the whole alphavirus genome or whether the first sequence encompasses two wholly complementary, non-contiguous fragments of the alphavirus genome.

The RSV proteins encoded by the second DNA sequence are not clearly set forth for reasons of record. The phrase "a second DNA sequence encoding the F or G glycoprotein of RSV or a truncated F or G glycoprotein of RSV lacking the transmembrane anchor and cytoplasmic tail" would overcome this rejection.

The phrase "a pair of splice sites that prevent aberrant mRNA splicing *in vivo*" is indefinite. It is unclear to what the phrase refers. The metes and bounds of what applicants consider aberrant splicing cannot be determined. Therefore, the metes and bounds of splice sites that prevent aberrant mRNA splicing *in vivo* cannot be determined.

Claim 8 remains indefinite because it is unclear if "the alphavirus" refers to the alphavirus in the "alphavirus RNA genome" or the "complete alphavirus RNA genome replication regions." Applicants' argument that the claim is clear is incomplete. No reasoning has been provided. It cannot be determined which is being further limited.

Claim 9 remains indefinite because the first DNA sequence is not clearly further limited. The phrase "the Semliki Forest viral sequence contained in plasmid pSFVI" lacks antecedent basis in claim 1. It is unclear whether "the Semliki Forest viral sequence" is the entire genome or a fragment thereof. Thus, the metes and bounds of the first DNA sequence encompassed by claim 9 cannot be determined.

***Claim Rejections - 35 USC § 102***

IV. Claims 1, 6, 8-10, 14-16 and 18 remain rejected under 35 U.S.C. 102(e) as being anticipated by Parrington (US Patent 6,060,308, May 9, 2000) for reasons of record.

Parrington taught an SFV vector expressing the F protein of RSV. The SFV portion of the vector is the "first DNA sequence" claimed. The nucleic acid sequence encoding the F protein of RSV is the "second DNA sequence" claimed. The "second DNA sequence" is downstream of the "first DNA sequence" (see Fig. 1C). The DNA just before the "second DNA sequence" is the "third DNA sequence" because the sequence can be spliced at any two sites. The promoter is the SP6 promoter (see Fig. 1C). The "third DNA sequence" is located between the promoter and "first DNA sequence." The three sequences are under the control of the SP6 promoter. The CMV immediate early promoter and rabbit  $\beta$ -globin intron II were used (col. 4, line 11).

Applicants argue Parrington did not teach the third DNA sequence claimed. Applicants' argument is not persuasive because the DNA just before the "second DNA sequence" and after the promoter is the "third DNA sequence" as claimed. The sequence can be spliced at any two sites. Without evidence to the contrary, the

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sequence has splice sites that prevent aberrant mRNA splicing *in vivo* because the metes and bounds of such splice sites cannot be determined (see 112/2<sup>nd</sup>).

Applicants argue that Parrington does not teach a vector encoding the CMVIE promoter or rabbit  $\beta$ -globin intron II. Applicants' argument is not persuasive. Claims 1, 6, 8-10 and 18 do not require such elements. In addition, Parrington described using the vector and elements required to preventing aberrant splicing described in WO 96/40945 with the vector described by Parrington. Therefore, Parrington taught SFV vectors encoding the F or G proteins of RSV comprising the CMVIE promoter and rabbit  $\beta$ -globin intron II that prevent aberrant splicing.

Applicants argue WO 96/40945 does not teach a Semliki Forest virus. Applicants' argument is not persuasive. The rejection is based on Parrington, which taught the Semliki forest virus. In addition, claims 1, 6, 10 and 14-16 do not require Semliki virus.

### ***Claim Rejections - 35 USC § 103***

V. Claims 1, 6, 8-10, 14-16 and 18 remain rejected under 35 U.S.C. 103 as being unpatentable over Dubensky (US Patent 5,814,482, Sept. 29, 1998) in view of Li (WO 96/40945, Dec. 19, 1996) for reasons of record.

Dubensky taught an alphaviral vector encoding RSV proteins (claim 10 of '482). The alphaviral vector sequence is the "first DNA sequence" and the DNA encoding the RSV protein is the "second DNA sequence" as claimed. The alphavirus of Dubensky is Semliki forest virus (col. 11, line 67) and is equivalent to the sequence contained in

plasmid pSFVI (claim 9 of this application). The limitation of the third DNA that comprises a pair of splice sites that prevent aberrant splicing is equivalent to the DNA sequence upstream of the alphavirus sequence and downstream of the promoter (see Fig. 8). Without evidence to the contrary, the sequence has splice sites that prevent aberrant mRNA splicing *in vivo* as claimed because the metes and bounds of such splice sites cannot be determined (see 112/2<sup>nd</sup>).

Dubensky does not teach the nucleic acid sequence of the RSV F or G proteins.

However, at the time of filing, Li taught a vector encoding the RSV F and G proteins under the control of the CMV immediate early promoter and comprising the rabbit  $\beta$ -globin intron II (pg 14, lines 5-21).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the expression vector encoding RSV proteins taught by Dubensky to deliver the F or G protein taught by Li. Li provides motivation by stating the F or G proteins induce an immune response in a host (pg 15, line 17). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an alphaviral vector encoding an RSV protein as taught by Dubensky wherein the F or G protein of RSV are used with the rabbit  $\beta$ -globin intron II sequence between the alphavirus sequence and the CMVIE promoter as suggested by Li (pg 14, line 10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to place the HDV ribozyme on the 3' end of the alphavirus sequence to insure deletion of the polyA termination sequence as suggested by Dubensky (col. 71, line 17) who also place the HDV ribozyme on the 3' end of the alphavirus sequence.

Applicants argue the third DNA sequence of Dubensky does not have a pair of splice sites but do not address why. Claiming a vector having a third sequence having a pair of splice sites that prevent aberrant mRNA splicing *in vivo* does not adequately define the structure or function of the third sequence such that the DNA between the alphaviral DNA and the promoter taught by Dubensky must be excluded from the claim. Without evidence to the contrary, the third DNA sequence of Dubensky inherently has the structure and function claimed.

### ***Double Patenting***

VI. Claims 1, 6, 8-10, 14-16 and 18 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 6, 8 and 18-21 of U.S. Patent No. 6,060,308. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of '308 is directed toward a vector having a portion of an SFV RNA genome and a sequence encoding an RSV F protein both under the control of a promoter (see pMP37, Fig. 1C). Thus, the first and second DNA sequences claimed in the instant invention are the SFV sequence and RSV F sequence in claim 1 of '308. The vector in claim 1 of has the third DNA sequence as required in claim 1 of the instant invention because the metes and bounds of a sequence having a pair of splice sites that prevent aberrant mRNA splicing in vivo and because the disclosure of '308 taught inserting the rabbit  $\beta$ -globin gene in between the promoter and alphavirus sequence to prevent aberrant splicing (col. 4, lines 20-25). Therefore, the vectors claimed have obvious additions to the vector of '308 and are explicitly taught in the disclosure of '308. Applicants' arguments have been considered but are not persuasive.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

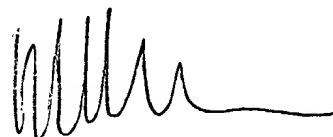
Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at 571-272-0738.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson



MICHAEL WILSON  
PRIMARY EXAMINER